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Carolyn M. Pengidore

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Dubious Practice? The Storm Over Physician Self-Referrals

I. INTRODUCTION

Put yourself, for a moment, in a rather grim situation: Your doctor says you have cancer. As part of the treatment, he proposes radiation therapy and refers you to an outpatient radiation center. He owns stock in the company that owns the center.

Should he tell you?

If, for him, the investment is substantial, should he reveal that?

Indeed, if he stands to make more than 10 times his money in two years, do you want to know?

Or, might you find the whole idea repugnant and feel that doctors should be barred altogether from referring patients to facilities in which they have a financial interest?

Such questions are not hypothetical. Businesses which provide radiation treatment and other medical services to patients have sprung up around the country. Many of these are financed by doctor-stockholders who will profit by referring their patients to these physician-owned facilities.¹ But federal and state regulators have started clamping down on doctor-stockholders who become involved in these business ventures.² What has developed is an increasingly heated national debate over the propriety of self-referral.³ At issue is the basic question of whether doctors should make

1. A study by state regulators in Florida recently found that 40 percent of doctors surveyed had invested in medical ventures to which they could recommend patients. State of Florida Health Care Cost Containment Board, *Joint Ventures Among Health Care Providers in Florida* (1991). The American Medical Association says only about 10 percent of American physicians are involved in such ventures, while other health care authorities have placed the estimate at 25 percent. American Medical Association, Council on Ethical and Judicial Affairs, *Conflicts of Interest: Physician Ownership of Medical Facilities*, *Journal of the American Medical Association*, 267, 2366 (May 6, 1992); Michael Waldholz and Walt Bogdanich, *Doctor-Owned Labs Earn Lavish Profits In A Captive Market*, *Wall Street Journal*, A1 (March 1, 1989).

2. A spokeswoman for the Office of Inspector General noted that the Department of Health and Human Services is currently investigating more than 200 cases around the country of alleged instances of physicians receiving kickbacks from facilities to which they refer Medicare patients. Glenn Ruffenach, *Medical Firms' Stocks Plunge on Probe News*, *Wall Street Journal*, B6 (June 26, 1992).

3. The term "self-referral" is used throughout this comment to mean referral by a

money by steering patients to facilities in which they have a financial stake—whether it is for radiation therapy, diagnostic tests, lab work, home infusion or rehabilitation.

The storm over physician self-referrals began brewing some years ago when formal studies, such as the one done by the Department of Health and Human Services' Inspector General's office in May, 1989, discovered that, for example, patients of referring doctors who invested in clinical labs received 45 percent more services than Medicare patients in general.⁴ This comment outlines the growing federal and state legislation targeted at self-referral practices, along with key cases which illustrate the latest judicial views on interpreting the medicare fraud and abuse statute as applied to self-referral situations. Federal regulatory efforts by the Office of the Inspector General and the Federal Trade Commission to curb abuse by physician-investors are also highlighted, as well as the conflict over the issue within the medical community. Set in the background of increasing economic pressure from rising health care costs, this article will provide the practitioner with a clear picture of how the legal risks are increasing for doctors who engage in self-referral activity.

II. THE MEDICARE ANTI-KICKBACK STATUTE

A. *Medicare and Medicaid Reimbursement Programs*

Medicare and other insurers reinforce the role of the physician in procuring ancillary services by paying only for those determined to be medically necessary and, as such, ordered by a physician.⁵ Medicare provides federal monies for medical services received by eligible persons who are over age 65, disabled, or have end-stage renal disease.⁶ The Medicare program is administered by the Health Care Financing Administration of the Department of Health and Human Services. Physicians receive payment for treat-

physician to a provider with whom the physician has a significant financial relationship.

4. Office of the Inspector General, Department of Health and Human Services, *Financial Arrangements Between Physicians and Health Care Businesses, Report to Congress* (Doc. No. OAI-12-88-01410) (May 1989), ["OIG Report"].

5. 57 Fed Reg 8589 (1992).

6. 42 USCA §1395c (1991). Medicare Part A is the Hospital Insurance (HI) program which provides reimbursement for services performed by hospitals and other institutional providers. HI recipients must pay a set deductible and coinsurance amount to receive services. Part B is the Supplementary Medical Insurance program which covers physicians' services and related expenses. It is subject to an annual deductible and usually pays 80 percent of reasonable charges. *Id.* at §1395j.

ing Medicare beneficiaries by submitting an application for Medicare reimbursement to a federally-approved insurance carrier.⁷

Medicaid is a joint federal-state program that provides payments for medical services received by the poor, the disabled, the elderly, and other qualified recipients.⁸ Medicaid programs are administered by state agencies, but are subject to federal regulatory guidelines.⁹ Physicians submit reimbursement applications for treating Medicaid beneficiaries directly to the state agency.¹⁰ The federal government contributes 50-80 percent of program costs (depending on the per capita income of the state) and the state covers the remaining costs.¹¹

Hospital reimbursement under Medicare is based upon a prospective payment system (PPS).¹² Under PPS, reimbursements are based on a fixed, predetermined sum for the treatment rendered. This sum is determined by the "average cost of treating a patient in a particular diagnostic-related group," regardless of the actual cost of the treatment.¹³ Under this program, the provider loses money if a Medicare patient's cost of care exceeds the prospective payment.

Prior to 1992, Medicare and Medicaid programs reimbursed physicians based on a retrospective system of payment. Reimbursement was based on the actual cost of delivering medical services to patients. But in 1989, Congress mandated reform of Medicare physician payment practices in order to redistribute Medicare money more fairly among physicians.¹⁴ Resource-based relative value scales (RBRVS) became effective January 1, 1992, with a four year phase-in period.¹⁵ Under RBRVS, reimbursement is based on the physician's work, practice expenses, and malpractice

7. 1 Medicare & Medicaid Guide (CCH) ¶3350 (Aug 1989).

8. 42 USCA §1396 (1991). Because Medicaid is a welfare program, eligibility is generally related to economic need and every Medicaid applicant must show that his or her income and resources fall below certain levels set by the states pursuant to federal guidelines. Medicaid represents a policy decision to provide welfare only to the deserving poor. 3 Medicare & Medicaid Guide (CCH) ¶14,211 et seq (Mar 1992).

9. 3 Medicare & Medicaid Guide (CCH) ¶14,010 (Jul 1989).

10. *Id.*

11. 3 Medicare & Medicaid Guide (CCH) ¶14,905 (Dec 1990).

12. Social Security Amendments of 1983, Pub L No 98-21 § 60-107, 97 Stat 65, 149-72 (1983). For an account of the Medicare system surrounding the change to and enactment of PPS, see generally Hyman and Williamson, *Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 Loy U Chi LJ 1133, 1136-43, 1166-69 (1988).

13. *Id.* at 1138-1143.

14. Omnibus Budget Reconciliation Act of 1989, Pub L No 101-239, 6102, 103 Stat 2169 (1989).

15. 42 USCA §1395w-4 et seq (1991).

costs.

As a result of these limitations on Medicare and Medicaid reimbursement, hospitals and doctors have embarked on a variety of revenue-enhancing ventures.¹⁶ Concerned about the costs of excessive utilization, Congress enacted Medicare and Medicaid fraud and abuse laws in an attempt to police provider conduct to control costs, protect quality, and encourage professional fidelity to patient interests.

B. Federal Anti-Fraud and Abuse Statute

Section 1128B(b) of the Social Security Act provides criminal penalties for individuals or entities that "knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare or state health care programs."¹⁷ The offense is classified as a felony, and is punishable by fines of up to \$25,000 and imprisonment for up to five years.¹⁸

This provision is extremely broad. The types of remuneration covered specifically include kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind.¹⁹ In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service or item paid for by Medicare or state health care programs.²⁰

16. For example, a review of the IRS Form 990 of one local hospital revealed a joint venture between the hospital and staff physicians established to operate a cancer treatment center. The hospital created a wholly-owned subsidiary which leased land from the hospital and built the treatment facility. The subsidiary was the general partner in a limited partnership which subleased the facility from the subsidiary and operated the center. Staff physicians invested in the operation as limited partners and referred patients to the facility. The hospital entered into a management contract with the partnership for management of the facility, thus receiving tax-exempt income through its wholly-owned subsidiary's share of partnership income, rental receipts, and its management fee. Allegheny General Hospital, Form 990 (for fiscal year-ending June 30, 1990).

Nonprofit hospitals participating in hospital-physician joint ventures which engage in self-referral activity may jeopardize their tax-exempt status under section 501(c)(3) of the Internal Revenue Code. The IRS has reversed its position on certain hospital-physician joint ventures within the last year. Where a hospital forms a joint venture with members of its medical staff, selling to the joint venture the gross or net revenue stream derived from the operation of an existing hospital department or service, the transaction jeopardizes the hospital's tax-exempt status. IRS General Counsel Memorandum 39862 (November 11, 1991).

17. 42 USCA §1320a-7b(b) (1991).

18. *Id.*

19. *Id.*

20. *Id.*

The Medicare and Medicaid Patient and Program Protection Act of 1987 added two new provisions addressing the anti-kickback statute. Section 2 provided new authority to the Office of the Inspector General ("OIG") to exclude an individual or entity from participation in Medicare and state health care programs if it is determined that the party has engaged in a prohibited remuneration scheme.²¹ These civil sanction provisions were intended to provide a remedy, short of criminal prosecution, for regulating abusive business practices.²² The OIG has aggressively pursued enforcement of these provisions which allow civil penalties and exclusion of providers from the Medicare program.²³ The civil sanction proceedings are administrative in nature, criminal intent need not be shown, and the standard of proof is preponderance of the evidence rather than beyond a reasonable doubt.²⁴

On their face, these provisions seem to proscribe a wide variety of transactions generally common in the economy, and arguably of value in the health care arena. Practices that may encourage competition or efficient production of health care might, under a literal reading of the fraud and abuse statute, be felonies under the federal law. Considerable effort, therefore, has been made by the judiciary to identify approaches that interpret the statute in order to separate beneficial and detrimental conduct.

C. *Judicial Interpretation of the Anti-Kickback Provision*

In *United States v. Greber*,²⁵ the court held that if payments were made to a physician to induce future referrals, even if the payments were compensation for actual services rendered by the physician, the Medicare anti-kickback provision had been violated.²⁶ *Greber* involved a diagnostic services company (Cardio-Med, Inc.) which provided physicians with a Holter-Monitor.²⁷ After Cardio-Med had analyzed the data received from the moni-

21. 42 USCA §1320a-7(b)(7) (1991).

22. 56 Fed Reg 35952 (1991).

23. Civil penalties of up to \$2,000 per violation may be imposed on physicians who file false or fraudulent Medicare or Medicaid claims. 42 USCA §1395a-7a(a) (1991). Upon conviction of fraudulent behavior by a state or federal agency, convicted physicians may be excluded or suspended from the Medicare and Medicaid programs. *Id.* at §1320a-7.

24. 55 Fed Reg 12205, 12209 (1990).

25. 760 F2d 68 (3rd Cir 1985), *cert denied*, 447 US 988 (1985).

26. *Greber*, 760 F2d at 71.

27. *Id.* at 70. This device was worn for 24 hours by the patient and would record cardiac activity. A technician scanned the tape and recorded the data in a diary. *Id.*

tored patient, it would bill Medicare for this service.²⁸ The data was then returned to the physician along with a portion of the Medicare payment that supposedly covered interpretation fees for services the physician would perform after receiving the data.²⁹ These interpretation fees were provided to physicians even though Cardio-Med already had interpreted and evaluated the data.³⁰ Because the physician would receive a benefit from the arrangement, there was an incentive for the physician to retain an ongoing relationship with Cardio-Med for their services. Although the defense argued that the funds were for professional services rendered, the court concluded that where an intent to receive future referrals exists, the statute has been violated.³¹ *Greber* thus demonstrates that the proper inquiry in analyzing economic arrangements involving physician referrals is not whether there is some legitimate purpose or explanation for a payment, but whether one purpose of the payment is to induce future referrals.

Two other circuits have lent further support to a broad reading of the statute. In *United States v. Kats*,³² the partial owner of a medical clinic was convicted for conspiracy to commit Medicare fraud and for receipt of kickbacks in exchange for referral of Medicare payments. *Kats* concerned an arrangement between physician offices or clinics, a phlebotomy service ("THC"), and a clinical diagnostic laboratory ("Tech-Lab").³³ Under the arrangement, THC collected blood and urine samples from physician offices and medical clinics, and forwarded these laboratory specimens to Tech-Lab.³⁴ Tech-Lab performed the laboratory tests and billed the respective insurance programs, including Medicare and Medicaid.³⁵ Tech-Lab kicked back 50 percent of its proceeds to THC, which in turn paid out part of its proceeds to various physicians' offices and clinics, including a clinic owned by Yan Kats.³⁶ Kats and others were prosecuted and convicted under the statute.³⁷ In upholding Kat's conviction, the United States Court of Appeals for the Ninth Circuit became the first court specifically to adopt the holding in

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.* at 71.

32. 871 F2d 105 (9th Cir 1989).

33. *Id.* at 106.

34. *Id.* at 107.

35. *Id.*

36. *Id.*

37. *Id.*

Greber that "if one purpose of the payment is to induce future referrals, the Medicare statute has been violated."³⁸ The *Kats* court held that the statute is violated unless the payments are "wholly and not incidentally attributable to the delivery of goods or services."³⁹

United States v. Bay State Ambulance and Hospital Rental Service, Inc.,⁴⁰ involved a municipal employee who received payments as a consultant to an ambulance company and who played a role in the awarding of the city's contract for ambulance service to that company. The court rejected the defendant's contentions that no showing had been made that (1) the employee received any more than his consultant services were worth,⁴¹ (2) the consulting contract with the ambulance company was entered into with specific intent that the employee would influence the bid process (the employee received payments before the bid process began), and (3) the payments to the employee were conditioned upon his affecting the city contract.⁴² The court emphasized that the gravamen of a violation of the statute is "inducement" and not necessarily the structure of the arrangement.⁴³ The court said it was irrelevant that the payments might reflect the value of the employee's services because "giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments toward a particular recipient."⁴⁴ The court also rejected the contention that a violation requires proof that "the payee actually performed the improper acts for which he was paid."⁴⁵ The decision rendered in *Bay State* thus stands for the proposition that a payment intended to induce a referral (or in that case a recommendation to purchase) is illegal, even if it is not conditioned on or does not result in a referral. The inducement is illegal even if it is only *one* of several purposes of payment, so long as it is not merely incidental.⁴⁶

Limited partnerships, believed to be excluded from the scope of the anti-kickback and fraud provisions when properly structured,⁴⁷

38. *Greber*, 760 F2d at 69.

39. *Kats*, 871 F2d at 108, n1.

40. 874 F2d 20 (1st Cir 1989)

41. *Id* at 29.

42. *Id* at 36.

43. *Id* at 29.

44. *Id*.

45. *Id* at 34.

46. *Id* at 30.

47. Hamilton and Page, *Fraud and Abuse, The Treatment of Limited Partnerships*

have recently come under increased judicial scrutiny. *The Inspector General v. Hanlester Network*⁴⁸ involved the appeal of a ruling made by an Administrative Law judge in favor of the defendants in this first case to propose exclusion from participation in Medicare and Medicaid programs for acts proscribed under the anti-kickback statute.⁴⁹ Hanlester Network had issued private placement memoranda offering limited partnership shares in three clinical laboratories.⁵⁰ The number of investors in each partnership was limited to 35 individuals or entities, with offerings limited to licensed physicians actively practicing in the laboratory's geographical area and to others whose ownership of shares would (in the promoter's judgment) benefit the laboratory.⁵¹ Business was solicited from both partner and non-partner physicians, but the limited partners were targeted as the primary source of partnership business.⁵² The private placement memoranda indicated that a partner's return on investment would be based on partnership profits, not the number of referrals.⁵³ The prospective partners were told they could expect an annual profit of greater than 50 percent of their investment.⁵⁴

The Inspector General alleged that distributions offered or paid by limited partnership laboratories to physician investors in a position to refer Medicare and Medicaid patients for tests were knowingly and willfully offered or paid as "remuneration . . . to induce"

and Physician Recruitment and Incentive Plans Under Medicare and Medicaid Fraud and Abuse Statutes, (Pennsylvania Bar Institute on Health Care Reimbursement, 1990). This article provides guidelines on what to avoid when structuring limited partnerships based on the then proposed safe harbor regulations (see note 70 and accompanying text), the OIG Report, the April 1989 OIG Fraud Alert on Joint Venture Arrangements, and the final version of the Stark amendment which added Section 1877, "Limitations on Certain Physician Referrals" to the Social Security Act. For example, the amount of the return should not be related to the referral volume; equal investment opportunities should be given to referring and non-referring investors; investing physician referrals should not be monitored by the entity; the rate of return should not be disproportionately large in relation to the investment, and financial disclosure should be made to the referred patient. The authors' positions are that despite the broad scope of the fraud and abuse statute, any per se prohibition against patient referrals by physician-investors is limited to those health care services or facilities which have a documented propensity for abuse.

48. CCH Medicare and Medicaid Guide, New Developments, ¶39,566, 27,739 (HHS Appeals Board, App Div, 1991).

49. *Id.* at 27,740.

50. *Id.* at 27,741.

51. *Id.* at 27,742.

52. *Id.*

53. *Id.*

54. *Id.*

referrals.⁵⁵ The key issue on appeal was whether the Inspector General had to prove that the offer or payment was conditioned upon the physicians agreeing to refer Medicare and Medicaid business to the laboratory, so that the physicians' choice of laboratories was precluded.⁵⁶

Ruling in favor of the Inspector General, the Appeals Board held that a violation of the anti-kickback statute occurs whenever an individual or entity knowingly and willfully offers or pays anything of value, in any manner or form, with the intent of exercising influence over a physician's reason or judgment in an effort to cause the referral of Medicare-related business.⁵⁷ The lack of an agreement requiring referrals, and the lack of proportionality between referrals by and returns to referring partners was not determinative.⁵⁸ The Appeals Board reasoned that because: (1) every referral made by a limited partner would cause incremental increases of his payment, (2) most of the referrals and the resulting revenue came from limited partners, and (3) partners were told that their referrals were essential to the venture's success, it could be inferred that the limited partners were aware of the potential impact of their referral decisions on their future income.⁵⁹ Addressing the fact that not all limited partners had made referrals, the Appeals Board ruled this did not prove a violation did not occur, and further stated that it wasn't necessary for the OIG to show that a payment actually succeeded in inducing a referral for it to have been intended to serve as an inducement.⁶⁰ The Appeals Board said that inferences regarding intent may be drawn from the structure of the venture: whether the offering is limited to potential referral sources; whether the investments were sought for capital needs of the venture; whether the venture met a need for services in the community; and whether the structure was designed to permit physicians to evade restrictions on their profiting from tests they order by taking advantage of the reference laboratory exception.⁶¹ Inferences regarding intent may also be drawn from the degree of nexus between the remuneration and the referrals.⁶² Even

55. Id at 27,740.

56. Id.

57. Id at 27,739.

58. Id at 27,741.

59. Id at 27,755.

60. Id.

61. Id at 27,763.

62. Id.

where payments are not made in proportion to actual referrals, the smaller the number of partners, the greater the impact each physician's referrals will have on his return and the greater his incentive to refer.⁶³ In reviewing evidence of an intent to induce referrals, the Appeals Board stated it will consider whether the value offered was sufficient to interfere with the physician's judgment based on legitimate considerations, such as cost, quality, and necessity of service.⁶⁴ The Appeals Board did not believe a finding of actual harm to the Medicare program was necessary to show a basis for exclusion, but viewed evidence which does show overutilization or reduced quality of services as relevant to determine whether the incentive offered was sufficient to induce referrals.⁶⁵ The Appeals Board remanded the case back to the Administrative Law judge to amend his findings in light of their broader interpretation of the anti-kickback statute.⁶⁶

On remand, HHS Administrative Law Judge Steven Kessel found cause to exclude the Hanlester network from Medicare and Medicaid business for two years, and to permanently exclude the three individual labs.⁶⁷ The doctor-investors were not named in the Inspector General's action.⁶⁸

D. *Safe Harbor Provisions*

Subsection D of the Medicare Patient and Provider Protection Act of 1987 authorized the Secretary of HHS to promulgate regulations specifying those business and payment practices, or "safe harbors," that are not subject to criminal prosecution under 1128B of the Act and that will not provide a basis for exclusion from the Medicare program or from state health care programs under section 1128(b)(7) of the Act.⁶⁹ The proposed safe harbor regulations were issued by the OIG on January 23, 1989.⁷⁰ After a period for public comment, the final regulations were issued on July 29,

63. *Id.*

64. *De minimis* or very remote forms of remuneration, such as drug samples or recruitment lunches, may not be subject to prosecution. If the remuneration offered is unlikely to affect physician referral decisions, it is probably not intended to induce referrals, absent clear evidence to the contrary. *Id.*

65. *Id.*

66. *Id.* at 27,762.

67. Brian McCormick, *HHS Ruling Keeps the Heat on Physician Self-Referral*, *American Medical News*, 35, 5 (March 23, 1992).

68. *Id.*

69. 42 USCA §1320a-7b (1987).

70. 54 Fed Reg 8033 (1989).

1991.⁷¹

The following payment practices are safe harbors which, although potentially capable of inducing referrals of business under Medicare or a state health care program, will be protected from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute.

Congress did not intend to bar all investments by physicians in health care entities to which they refer patients where the investment interest was in a large public corporation and such investments are available to the general public.⁷² In order to qualify for the safe harbor for investment interests, the investor must meet the applicable standards within one of two classes of entities. In setting standards, the OIG differentiated between investments in large, publicly traded and small, privately held enterprises.

If the entity has more than \$50 million in tangible net assets, the following five standards apply:

- * First, if the investment is an equity security, it must be registered with the Securities and Exchange Commission.⁷³

- * Second, the investment by the referring physician must be obtained on terms equally available to the general public trading on a registered securities exchange.⁷⁴ Public trading assures that the entity does not obtain capital by self-selecting investors based on their status as sources of referrals.⁷⁵ Any investment interest obtained before the entity becomes publicly traded or obtained by physicians before the general public has an opportunity to invest is not protected.⁷⁶

- * Third, the entity must not market or furnish the entity's items or services to passive investors differently than to non-investors or participate in cross-referral arrangements.⁷⁷

- * Fourth, the entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the

71. 56 Fed Reg at 35952 (cited in note 22).

72. *Id.* at 35953 (cited in note 22).

73. 42 CFR § 1001.952 (1991).

74. *Id.*

75. 56 Fed Reg at 35965 (cited in note 22).

76. *Id.*

77. 42 CFR § 1001.952 (cited in note 72). A "cross-referral" arrangement exists when investors in entity "A" are explicitly or implicitly encouraged to refer to entity "B" in return for entity "A" receiving referrals from investors in entity "B". 56 Fed Reg at 35969 (cited in note 22).

investment interest.⁷⁸

* Finally, the amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.⁷⁹

All five standards must be met to the extent they apply to the investment in question. The intent behind protecting investors in large publicly traded stocks is that the remuneration received by these investors is so tangentially related to their referrals that the potential for abuse is minimal.⁸⁰

The OIG realized that a large number of newly formed entities are designed to have physicians as investors specifically to induce them to use the entity in which they have invested.⁸¹ Thus, the OIG attempted to include safeguards to minimize any corrupting influence the investment interest may have on the physician-investor's decision where to refer a patient.⁸² The provisions for investments in small entities were specifically written to cover limited and general partnership interests.⁸³

The first standard which must be met to achieve safe harbor protection for payments to investors in the entity is that investors who make referrals or furnish items or services cannot own more than 40 percent of the entity.⁸⁴ At least 60 percent of the entity must be held by investors who will neither make referrals nor engage in business with the entity.⁸⁵

The second standard focuses on the status of the investor and bars safe harbor protection where the terms of the investment opportunities depend on whether the "passive" investor (i.e. limited partner) is in a position to influence referrals or otherwise generate business for the entity.⁸⁶ Investments can be offered to such investors only on the same terms as to other passive investors who are not in a position to influence the flow of business to the entity.⁸⁷

The third standard requires that the terms on which the invest-

78. 42 CFR § 1001.952 (cited in note 73).

79. *Id.*

80. 56 Fed Reg at 35964 (cited in note 22). Investment in most publicly traded drug companies, for example, would fall under this exception. Thus, a physician can prescribe a drug manufactured by a publicly traded company in which the physician owns stock without risking criminal sanction. 54 Fed Reg 3094 (1989).

81. 56 Fed Reg at 35966 (cited in note 22).

82. *Id.*

83. 56 Fed Reg at 35967 (cited in note 22).

84. 42 CFR § 1001.952 (cited in note 73).

85. 56 Fed Reg at 35968 (cited in note 22).

86. *Id.*

87. 42 CFR § 1001.952 (cited in note 73).

ment is offered cannot be based on past or expected referrals or business generated for the entity.⁸⁸

The fourth standard bars the entity from requiring passive investors to make referrals or remain in a position to make referrals as a condition for retaining their investment.⁸⁹

The fifth standard parallels that for publicly traded entities and requires the entity and investors not to market or furnish items or services to passive investors in any manner differently than to non-investors.⁹⁰ An entity or investor may not promote the services of other entities as part of a cross-referral arrangement.⁹¹

The sixth standard requires that no more than 40 percent of an entity's gross revenue come from referrals, or items or services furnished by investors.⁹² Coupled with the first standard which requires 60 percent outside ownership, these two standards assure that the entity is not dependent on the capital and referrals of physician-investors.⁹³ The purpose behind these two requirements is to force these entities to compete for outside business.⁹⁴

The last two standards focus on financing and profit distributions. A condition of safe harbor protection is to assure that investments by referring physicians are bona fide, i.e., that investors' funds are genuinely at risk.⁹⁵ The seventh standard parallels that for investments in large publicly traded entities. These entities cannot lend or guarantee loans used to make the investment.⁹⁶ Where an investor makes an investment with money loaned to him from the entity, he adds no real capital to it. This standard was meant to assure the investors provide needed new capital and the joint venture is not a sham to facilitate the distribution of payments for referrals.⁹⁷

Finally, the eighth standard requires the amount of payment to each investor be directly proportional to capital investment.⁹⁸ In other words, to receive protection, dividend payments can only be tied to the number of shares owned by an investor, and not to

88. *Id.*

89. 56 Fed Reg at 35969 (cited in note 22).

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.* at 35970 (cited in note 22).

96. *Id.*

97. *Id.*

98. 42 CFR § 1001.952 (cited in note 73).

referrals.⁹⁹

Safe harbor protection was also extended to space and equipment rentals where there is a written lease for a minimum term of one year and the rental charges are set forth in advance and reflect fair market value in an arms-length transaction without regard to volume of referrals or business generated between the parties.¹⁰⁰ For example, hospitals that give rent concessions to staff physicians leasing private office space or equipment would not fall within the safe harbor.¹⁰¹ "Per use" or "per procedure" leases or contracts with referring physicians in which the compensation varies with actual use of premises or equipment are highly suspect under the fraud and abuse statute.¹⁰²

Personal service and management contracts will receive safe harbor protection provided they meet standards similar to those for space and equipment rentals.¹⁰³ Finally, safe harbor protection was extended to payments made for the sale of a practice; payments made to referral services that are related to the cost of operating such service and not based on volume of referrals; manufacturer or supplier warranty payments; certain buyer discounts; payments to employees or by vendors to a group purchasing organization; and waivers of beneficiary coinsurance and deductible amounts.¹⁰⁴

III. THE ETHICS IN PATIENT REFERRALS ACT

A. *Section 1877, "Limitations on Certain Physician Referrals"*¹⁰⁵

Introduced in the House of Representatives as the Ethics in Patient Referrals Act,¹⁰⁶ section 1877 of the Social Security Act prohibits physicians from making referrals for Medicare-financed services to clinical laboratories in which the physician (or an immediate family member) has a financial interest.¹⁰⁷ It is also ille-

99. 56 Fed Reg at 35970 (cited in note 22).

100. 42 CFR § 1001.952 (cited in note 73).

101. 56 Fed Reg at 35972 (cited in note 22).

102. *Id.* at 35973 (cited in note 22).

103. 42 CFR § 1001.952 (cited in note 73).

104. *Id.*

105. Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub L 101-239, enacted on December 19, 1989) added section 1877, "Limitations on Certain Physician Referrals," to the Social Security Act. In addition, section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub L 101-508, enacted on November 5, 1990) amended certain provisions of section 1877 of the Act.

106. This Act is often referred to as the "Stark Amendment," named after Rep. Fortney (Pete) Stark of California who introduced the bill in the House of Representatives.

107. 42 USCA §1395nn.

gal for a clinical laboratory to bill for services provided subject to such illegal referrals.¹⁰⁸ The Act became effective for referrals made on or after January 1, 1992.¹⁰⁹

The Act is subject to a number of exceptions. First, physicians may refer to laboratories supervised by other members of a group practice or HMO of which they are a part.¹¹⁰ Second, physicians may refer to laboratories in which they own publicly traded stock if the assets of the corporation exceed \$100 million.¹¹¹ Third, rural clinical laboratories are exempt.¹¹² Finally, physicians may refer to the laboratories of hospitals in which they have an ownership interest, by which they are employed, or from which they rent office space or have received physician recruitment incentives, if specific statutory requirements are met to assure that arrangements are in good faith and at arms-length.¹¹³

Sanctions for violations of the Ethics in Patient Referrals Act include denial of payment by Medicare; refunds to the Medicare beneficiary if any payment was received for a service provided pursuant to a prohibited referral; civil penalties of up to \$15,000 for each item or service provided pursuant to a prohibited referral; exclusion from the Medicare program for both the physician and the provider; and civil penalties of up to \$100,000, along with exclusion from the Medicare program if the referral is made in connection with a circumvention scheme such as a cross-referral arrangement.¹¹⁴

The Act was passed to close a loophole in the Medicare anti-kickback statute which allowed promoters to disguise referral schemes as legitimate business arrangements. Such arrangements typically involved partnerships with referring physicians, consulting arrangements, and franchise corporations wholly-owned by physician investors with the service provider as manager.

While the legislative history to the Act cites numerous examples of fraud and abuse in the areas of radiation therapy, physical therapy, and diagnostic testing facilities, the final version of the Act was reduced from a general prohibition against self-referrals by physicians to a selective prohibition against the referral of Medi-

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

care or Medicaid patients to clinical laboratories.¹¹⁵

B. Proposed Rulings to Implement Federal Ban on Self-Referrals of Medicare Patients to Clinical Laboratories

On March 11, 1992, the Health Care Financing Administration (HCFA) published its proposed rulings to incorporate section 1877 of the Social Security Act into its regulations.¹¹⁶ The newly released regulations were published after Medicare carriers surveyed entities that had billed them for lab services within the past year, asking for detailed ownership information.¹¹⁷

The proposed rulings use terms similar to those used within the OIG's anti-kickback safe harbor provisions, but emphasize that the two sets of rules are independent of each other.¹¹⁸ The HCFA noted that referrals for clinical laboratory services to be furnished for a physician's non-Medicare patients are not affected by the proposed rule.¹¹⁹ The HCFA also stated that a physician who has no financial relationship with a clinical laboratory outside his own office would not be affected by the proposed rule unless ordering clinical laboratory services under a consultation request from another physician who does have a financial relationship with the laboratory, or who is participating in a "contravention scheme."¹²⁰

Financial relationships entered into in order to comply with the new provisions of the Act are not exempt if they do not qualify under one of the statutory exceptions.¹²¹ For example, if a group of physicians attempted to sell a laboratory by January 1, 1992, in order to comply with the referral prohibition, but sold it for a fixed price with installment payments that extend beyond the January 1, 1992, effective date, the physicians would still be precluded from making referrals to the laboratory.¹²² This is because physicians

115. The OIG Report revealed that at least 25 percent of the nearly 4500 independent clinical laboratories surveyed were owned in whole or in part by referring physicians, and provided overwhelming evidence of abuse in the utilization of physician-owned clinical laboratories. 57 Fed Reg at 8589 (cited in note 5)

116. 57 Fed Reg at 8588 (cited in note 5) (to be codified at 42 CFR § 411j).

117. Diane M. Gianelli, *Clamping Down on Self-Referrals*, American Medical News, 35, 1 (April 6, 1992).

118. 57 Fed Reg at 8595 (cited in note 5).

119. *Id.*

120. *Id.* The HCFA recommends that attending physicians provide the consulting physician with a list of laboratories from which the consulting physician should not order services. *Id.*

121. *Id.*

122. *Id.*

who receive installment payments from the sale of their laboratory have an incentive to refer business to the laboratory to maintain its financial viability until all payments are received.¹²³

The proposed rulings also extend the prohibition to situations where Medicare benefits are secondary to benefits paid by third party payers, such as employer group health plans.¹²⁴ Entities which furnish clinical laboratory services under prohibited referrals may not bill the employer group health plan for their services.¹²⁵

The proposed rulings outline exceptions which apply to specific services including: physicians' services in a group practice, in-office ancillary services, and services furnished to prepaid health plan enrollees.¹²⁶ For example, the prohibition does not apply in the case of physicians's services provided personally by another physician in the same group practice as the referring physician, but the proposed rulings strictly define "group practice" in such a way as to outlaw many shared lab arrangements.¹²⁷

An exception is also made for investments in publicly traded securities where the corporation has total assets which exceed \$100 million.¹²⁸ Like the anti-kickback safe harbor provisions, the proposed regulations require that the stocks be purchased on terms generally available to the general public. The \$100 million in assets requirement applies only to the corporate entity which furnishes the clinical laboratory services, and assets of a related corporation (for example a parent, subsidiary, or sister corporation) may not be considered in qualifying the laboratory under the \$100 million asset test.¹²⁹ The HCFA also proposed that the assets must be obtained within the normal course of business, any assets obtained primarily for the purpose of meeting the \$100 million requirement would be excluded from consideration.¹³⁰

Specific providers are also excluded from the prohibition on re-

123. Id at 8596 (cited in note 5).

124. Id.

125. Id.

126. Id.

127. A "group practice" is defined as a group of two or more doctors legally organized as a partnership, professional corporation, foundation, non-profit corporation, faculty practice plan or similar legal entity. But several independent practitioners who enter into a partnership to provide lab services for their individual practices will not qualify for the exemption. Id.

128. Id at 8597 (cited in note 5).

129. Id.

130. Id.

ferrals, including laboratories located in rural areas. In order to prevent this rural laboratory exception from being abused, the HCFA proposed to add a requirement that at least 51 percent of tests referred to the rural laboratory must be referred by physicians who have offices in the rural area.¹³¹ This requirement is meant to assure that the laboratory is in fact serving rural beneficiaries, and is not simply located in the rural area for the purpose of furnishing services referred by urban owners for their urban patients.¹³² The rural laboratory is also required to operate as a full-service laboratory and cannot be a "shell" lab with a rural address.¹³³ When physician-investors refer to a rural lab, the tests must be performed on the lab's premises.¹³⁴ If a referral to another lab is necessary, tests must be billed by the lab that performs them.¹³⁵

The proposed regulations also specify exceptions for hospitals in Puerto Rico, ownership in hospital laboratories, and certain other compensation arrangements.¹³⁶

IV. PHYSICIAN SELF-REFERRAL AMENDMENTS OF 1992

On July 1, 1992, the House Ways and Means Health Subcommittee passed H.R. 5142, the Physician Self-Referral Amendments of 1992.¹³⁷ Cosponsored by Rep. Kasich (Ohio) and Rep. Santorum (Pa.), the bill would amend section 1877 of the Social Security Act to extend the ban on physician self-referrals to all payers and to radiology and diagnostic imaging services, radiation therapy services, physical therapy services, and durable medical equipment.¹³⁸ The Act also adds exceptions for managed care facilities and health maintenance organizations, as well as a waiver for valuable community service when approved by the Secretary of Health and Human Services.¹³⁹ The Act proposes a divestment period of two years for physicians with an investment in an affected facility, and

131. Id at 8598 (cited in note 5).

132. Id.

133. Id.

134. Id.

135. Id.

136. Id.

137. Glenn Ruffenach, *T2 Medical's Dazzling Prospects Becoming Tarnished*, Wall Street Journal, B8 (July 7, 1992).

138. Physician Self-Referral Amendments of 1992, HR 5142, 102d Cong, 2d Sess (May 12, 1992).

139. Id.

is otherwise effective six months after enactment.¹⁴⁰

The bill will now move to the full committee where it is expected to face stiff opposition, even though the Bush administration has come out in favor of outlawing physician self-referrals.¹⁴¹

V. ANTITRUST CONCERNS

For physicians who thought the only legal risk they ran by investing in medical joint ventures was drifting outside Medicare's safe harbor provisions, they need to think again. In a speech to the National Health Lawyers Association, FTC Competition Director Kevin Arquit warned that doctors who refer patients to firms in which the doctor has a financial interest are being closely examined by the Federal Trade Commission.¹⁴² The aim is to stop anti-competitive behavior by physicians as part of the FTC's effort to use antitrust laws to help control rising health care costs.

Arquit stated that the FTC is "aggressively pursuing several investigations" of self-referrals which could result in prosecution and government-ordered breakups of physician joint ventures.¹⁴³ The focus of these investigations are physician joint ventures formed to provide services or goods in a market outside of, but functionally related to, the participating physicians' professional practice.¹⁴⁴ The typical joint venture involves a group of physicians forming a partnership to set up a clinical laboratory, a physical therapy center, or a diagnostic imaging facility. Arquit pointed out that the same physician-owner incentives for self-referral that lie at the heart of the conflict-of-interest issue also give rise to antitrust concerns: the potential for creating or enhancing market power in markets for ancillary goods or services, which result in higher prices and lower quality health care to consumers and monopoly profits to some health care suppliers.¹⁴⁵

The principal antitrust concern with physician joint ventures is the creation or enhancement of market power in the market for the particular ancillary goods or services offered by the joint venture.

140. *Id.*

141. Sharon McIlrath, *Dr. Sullivan Hit Hard Backing Bush Reform Plan*, *American Medical News*, 35, 1 (March 9, 1992).

142. Kevin Arquit, Director, Bureau of Competition, Federal Trade Commission, *A New Concern in Health Care Antitrust Enforcement: Acquisition and Exercise of Market Power by Physician Ancillary Joint Ventures*, speech before the National Health Lawyers Association (January 30, 1992).

143. *Id.*

144. *Id.*

145. *Id.*

If such market power has been attained, the antitrust laws may have been violated because the entity was created by the aggregation of competitors into a single dominant venture or by other exclusionary conduct. In describing physician-owned joint ventures which give rise to antitrust concerns, Arquit expanded on the concept of achieving market share by controlling access—what he called “channeling” patients—through the ability to make referrals. He stated that the antitrust significance of physician channeling to doctor-owned facilities turns on the efficacy of such channeling, and not on the particular mechanism by which it is carried out.¹⁴⁶

Arquit outlined several antitrust legal theories which could be used to challenge physician-owned ventures. Proceeding on a Sherman Act section 2 monopolization theory,¹⁴⁷ the agency could charge doctors with forming an illegal monopoly.

The FTC could also use section 7 of the Clayton Act to attack joint ventures which could “substantially lessen competition.”¹⁴⁸ A third approach looks to section 1 of the Sherman Act¹⁴⁹ and focuses on proving an agreement among the joint venturers to refer all patients to the venture to the exclusion of competitors. Explicit proof of the agreement would not be necessary in such a case, but may be found implicit in the process by which the venture was formed.

Recent court of appeals decisions¹⁵⁰ also could be used to prosecute hospitals for attempted monopolization under section 2 of the Sherman Act when the hospital steers discharged patients to a particular supplier in which the hospital has a financial interest.

Finally, pricing policies used by physician joint ventures may arouse antitrust concerns. Where the only integration among physicians is in ownership of equipment, and the physician-owners’ medical practices remain separate, an agreement among them on the price they will charge for their independent delivery of medical services, can under certain circumstances, be viewed as *per se* unlawful horizontal price fixing. And, physicians who condition the provision of medical treatment on the purchase of ancillary ser-

146. *Id.*

147. 15 USC §2 (1975).

148. 15 USC §18 (1975).

149. 15 USC §1 (1975).

150. *Key Enterprises of Delaware, Inc. v Venice Hospital*, 919 F2d 1550 (11th Cir 1990); *Advanced Health-Care Services, Inc. v Radford Community Hospital*, 910 F2d 139 (4th Cir 1990).

vices from their joint venture may be subject to a tying violation.

VI. STATE LEGISLATION

Despite the broad federal provisions, state legislators have taken up the cause against self-referral as well. Two dozen bills are currently pending in various state legislatures to curb self-referrals.¹⁵¹ The scope of state legislation currently on the books varies from disclosure requirements¹⁵² to outright bans on the practice.¹⁵³

In April, 1992, Florida legislators approved a strict measure that both capped fees and prohibited self-referral to various facilities. Considered landmark legislation on the issue of self-referral, the Florida bill, with a few exceptions similar to those found in the federal safe harbor provisions, bans all doctor self-referrals for clinical lab tests, diagnostic imaging, rehabilitation and radiation therapy effective July, 1992.¹⁵⁴ The legislature also capped all fees at 115 percent of the Medicare rate — regardless of who picks up the tab.¹⁵⁵

The impetus behind the Florida legislation was a three-volume report by the Florida Health Care Cost Containment Board released last fall which uncovered abusive self-referral practices in doctor-owned labs, diagnostic imaging, and rehabilitation centers.¹⁵⁶ The Florida study disclosed that two out of every five doctors in the state had an interest in a venture to which they could

151. Thomas M. Burton, *Physicians Who Own Labs May Refer Patients to Them for Tests*, *AMA Says*, *Wall Street Journal*, B6 (June 24, 1992).

152. Pennsylvania, for example, requires that prior to referral, a health care provider must disclose to the patient any financial interest or ownership in the facility and advise the patient of his freedom to choose in selection of a facility. 35 Pa Cons Stat Ann §449.22 (Purdon 1991). Arizona, Delaware, Massachusetts, Minnesota, Nevada, Virginia, Washington, and West Virginia also have disclosure requirements. Teri Randall, *Good Intentions Do Pave Road to Save Harbors, But Taking Contravention Avenues Remains Risky*, *Journal of the American Medical Association*, 266, 2330 (November 6, 1991).

153. Michigan enacted one of the nation's toughest laws governing physician's conflicts of interest after a 1983 study by Michigan Blue Cross and Blue Shield comparing price and usage of 20 doctor-owned labs versus 20 independent labs revealed that doctors referring to facilities in which they had an ownership interest ordered on average almost twice as many tests as doctors referring to the independent labs, at 175 percent the per test cost of the independent labs. The Michigan law bars physicians from referring patients to medical facilities in which they have a financial interest. Waldholz and Bogdanich, *Wall Street Journal* at A1 (cited in note 1); Mich Stat Ann §14.15(16221) (Callaghan 1988 and Supp 1992).

154. Patient Self-Referral Act of 1992, Fla Stat §178 (1992).

155. *Id.*

156. State of Florida Health Care Cost Containment Board, *Joint Ventures Among Health Care Providers in Florida* (1991).

refer patients.¹⁵⁷ It further revealed that Florida doctors owned 93 percent of all diagnostic imaging centers in the state.¹⁵⁸ Doctors who engaged in self-referral were shown to order twice as many tests at an estimated cost to the state of \$500 million a year in unnecessary tests.¹⁵⁹ Moreover, the study concluded that physician-owned facilities provided limited access to services for rural or underserved indigent patients.¹⁶⁰

Other states are considering similar action. Both houses of the Tennessee legislature passed self-referral bills in the last legislative session at the end of April but postponed final deliberations until next year.¹⁶¹ The Tennessee Medical Association supports the less stringent Senate bill, which would ban referrals to off-site centers where physicians would not perform the service.¹⁶²

In Rhode Island, legislators are considering two bills that would curb physician self-referral. One is a comprehensive self-referral prohibition that would subject physicians to a 30-day loss of their medical license for initial violations, and the other is intended to regulate physician investment in pharmacies.¹⁶³ The latter legislation, which was approved in late April, does not ban physician referrals to pharmacies they own, but says that investment in pharmacies can constitute a reason for the state Pharmacy Board to deny or revoke a license of a drug-prescribing healthcare provider.¹⁶⁴

New York's Governor Cuomo has suggested a blanket ban on physician-investor referrals, while the neighboring state of New Jersey will allow referrals to physician-owned facilities in effect as of July 31, 1991, so long as disclosure is made, but has banned

157. *Id.*

158. *Id.*

159. Burton, Wall Street Journal at B6 (cited in note 151).

160. Testifying before the House Ways and Means Health Subcommittee at a hearing on physician ownership and referral arrangements, economist Jean Mitchell, an associate professor at Florida State University who conducted the Florida study, stated that many of the [physician-owned] joint ventures refuse Medicaid patients, and "none are located in medically underserved areas." This situation contradicts the contention that joint ventures improve geographic access to services. Fran Pollner, *Self-Referral Ban Wagon Rolls On: Rep. Stark Showcases More Negative Findings On Physician Ownership Of Ancillary Facilities In A Crusade That May Yet Encompass More Than Clinical Lab Owners*, Medical World News, 32, 15 (Nov 1991).

161. Peggy Peck, *States Curb Physician Self-Referral*, Medical World News, 33, 31 (May 1992).

162. *Id.*

163. *Id.*

164. *Id.*

referrals to arrangements formed after that date.¹⁶⁵ In Missouri, a bill which bans physicians from referring patients to physician-owned physical therapy centers has passed the Missouri House and is now before the state legislature.¹⁶⁶

The California House also passed a bill banning self-referrals¹⁶⁷ after a study conducted by the New York-based firm of William M. Mercer and funded by Industrial Indemnity of San Francisco, revealed that physician self-referrals for workers' compensation costs may be costing California employers more than \$350 million in workers' compensation costs annually.¹⁶⁸ The study entitled "*The Frequency of Provider Ownership and Investment on Referral Patterns in California Workers' Compensation and the Economic Impact of such Phenomena*" also concluded that twice as many patients are referred for physical therapy when a physician who initially treats the patient has an ownership in the physical therapy services, and that claims with a referral-for-profit relationship were 28 percent more expensive than those from independent ownership cases.¹⁶⁹

VII. CONCLUSION

The United States probably has the highest quality and most innovative health care system in the world, but can barely afford the system in place today or the cost burdens that threaten it over the next 40 years. The issue of health care cost and availability has been placed on the forefront of the American political agenda for a variety of reasons.

In 1991, health care expense was about 14 percent of gross domestic product (GDP), up from only 5 percent in 1960.¹⁷⁰ Absent reform, the aging population and a higher rate of inflation in health care services imply a 25 percent share of GDP by the year 2030.¹⁷¹ Health care costs totaled \$585.3 billion in 1990, and in the face of multi-billion dollar budget deficits, represented 13.3 per-

165. Terese Hudson, *States Extend Message of Stark Referral Bill*, Hospitals, 66, 62 (May 20, 1992).

166. Brian McCormick, *Physical Therapists Push Self-Referral Ban in Missouri*, American Medical News, 35, 6 (March 2, 1992).

167. Hudson, Hospitals, 62 (May 20, 1992).

168. Angela K. Calise, *Study Scrutinizes Use of Physician Self-Referrals*, National Underwriter Property & Casualty-Risk & Benefits Management, C4 (March 2, 1992).

169. Id.

170. William Dudley, *The U.S. Health Care Conundrum*, Goldman Sachs Economic Research, 1 (May 1992).

171. Id.

cent of total federal government expenditures in 1991.¹⁷² The situation at the state government level is similar. Total Medicaid spending climbed at a 11.3 percent annual rate between 1980 and 1990.¹⁷³ In 1991, Medicaid spending by the states averaged about 14 percent of total expenditures, up from about 9 percent in 1980.¹⁷⁴

About 35 million people in the United States do not have health insurance coverage¹⁷⁵ and businesses have scaled back employer-paid private insurance coverage in an attempt to cope with rising costs. Business health care spending as a share of total compensation has climbed significantly in recent years, to 7.1 percent of total compensation in 1990 from just 4.9 percent 10 years earlier.¹⁷⁶ Corporate health care costs amounted to a whopping 46 percent of profits in 1991, after increasing 12 percent from 1990.¹⁷⁷ Moreover, these costs do not come close to representing businesses' true liabilities.

The investment community has recently been stunned by the size of estimated costs to provide health care to retirees of U.S. corporations. Disclosure required by FAS 106 beginning in 1993 will force companies to show on their balance sheets the huge unfunded future liabilities for retiree health care benefits.¹⁷⁸ Estimates of the current national liability range from less than \$300 billion to \$2 trillion.¹⁷⁹ A new awareness of cost has enlightened the average worker as well, as employers have begun to shift the health care cost burden onto their employees. Health care has been a major issue in 75 percent of the labor strikes over the past 2 to 3 years.

In the face of these staggering statistics, the average doctor's income rose to \$132,300 in 1987, up from \$113,192 in 1970, outstripping the average gain in workers' incomes.¹⁸⁰ Average real weekly earnings for workers actually declined over the same period.¹⁸¹

172. Id at 5.

173. Id at 6.

174. Id.

175. Id at 1.

176. Id at 5.

177. Ron Winslow, *Firms Restrain Rate of Growth Of Health Costs*, Wall Street Journal, B1 (February 4, 1992).

178. Financial Accounting Statement No. 106, *Employers' Accounting for Postretirement Benefits Other Than Pensions*, Financial Accounting Standards Board (1990).

179. Sharon Kahn, *Companies Face Up to FAS 106*, Global Finance, 64 (December 1991).

180. Dudley, *The U.S. Health Care Conundrum* at 9 (cited in note 170).

181. Id.

There is little evidence that this increase occurred because doctors were previously underpaid. Doctors in the United States are paid far more than in other countries, both absolutely and relative to the average worker's income. According to a recent study by the Congressional Budget Office, in 1986 the ratio of physician's earnings to the average worker's earnings was 5.1 in the United States, compared with 4.3 for the former West Germany, 3.7 for Canada, 2.5 for Japan, and 2.4 for the United Kingdom.¹⁸²

The general public is likely to have little sympathy for wealthy doctors whose business practices skirt the grey areas of self-referral laws. Meanwhile, physician payment reform is likely to increase the potential for abuse as physicians seek income from joint venture facilities to supplement declining practice revenues.¹⁸³

The health care community itself is split over the issue of self-referral. At a recent meeting in Chicago, the governing body of the American Medical Association (AMA) sent shockwaves through the medical community when it reversed itself and endorsed the practice of self-referral.¹⁸⁴ The move by the AMA's House of Delegates runs counter to AMA ethical guidelines which currently condemn the practice.¹⁸⁵ The American College of Radiology, with its

182. Id at 10 (citing *Rising Health Care Costs: Causes, Implications, and Strategies*, Congressional Budget Office, April 1991).

183. *The Future of Healthcare: Physician and Hospital Relationships*, Arthur Anderson and American College of Healthcare Executives (1991).

184. Ruffenach, Wall Street Journal at B4 (cited in note 2). Resolution 5, introduced by the New Jersey Delegation at the June, 1992, meeting of the AMA's House of Delegates provides that "medically necessary referrals by a physician to an off-site facility in which he/she has a financial interest is ethical if the patient is fully informed of the ownership interest and the existence of any available alternate facilities." American Medical Association House of Delegates. The vote to endorse the practice of self-referral comes just six months after a unanimous vote by the House of Delegates to approve the AMA Council on Ethical and Judicial Affairs' position against self-referral.

185. Burton, Wall Street Journal at B6 (cited in note 151). The AMA Council on Ethical and Judicial Affairs has taken the position that, in general, physicians should not refer patients to a health care facility outside their office practice at which they do not directly provide care or services when they have an investment interest in the facility. Physicians may invest in and refer to an outside facility if there is a demonstrated need in the community for the facility and alternative financing is not available. *Current Opinions of the Council On Ethical and Judicial Affairs*, Code of Medical Ethics (1992).

Indeed, the Council recently strengthened its position and called for aggressive enforcement by state and county medical societies of the Council's existing guidelines on conflicts of interest. The Council published its latest report after having the AMA's Center for Health Policy Research review empirical evidence of overutilization and abuse in physician-owned facilities. The review validated the results of the OIG Report, the study issued by the Florida Health Care Cost Containment Board, and a third study entitled "*Frequency and Costs of Diagnostic Imaging in Office Practice — A Comparison of Self-Referring and Radiologist-Referring Physicians*," by Bruce Hillman which appeared in the *New England*

27,000 members, including both radiation oncologists and diagnostic radiologists, has come out strongly opposed to self-referral.¹⁸⁶ The group has gone so far as to testify before Congress in support of "legislative efforts prohibiting reimbursement for therapeutic procedures carried out in a facility in which the referring physician has a direct or indirect financial interest."¹⁸⁷ Lee F. Rogers, the Radiology College chairman, wrote in a personal letter to the editor of the *New England Journal of Medicine*: "We have found the potential and actual abuse and exploitation of patients by unethical practices, and the flagrant disregard of physician's responsibilities to the patient so great and so pervasive that these arrangements must be disallowed."¹⁸⁸

It's no surprise that many within the medical profession are against the practice. At risk is the doctor's reputation, as the general public may perceive the physician as just another entrepreneur who leaves no stone unturned in his efforts to make a buck. Dr. Arnold Relman, former editor-in-chief of the *New England Journal of Medicine*, argues that doctors profiting from self-referrals are involved in blatant conflicts of interest which would not be tolerated in the business world.¹⁸⁹ He points out that a purchasing manager at a major corporation who confides to his boss that he placed business with a supplier in which he had a vested interest would be summarily fired.¹⁹⁰ Or a judge who decides a case between two companies while holding stock in one of them, would be violating every canon of judicial behavior.¹⁹¹ Referring doctors serve as both concerned purchasing manager and impartial judge for their patients, and yet incredibly, try to argue that having an economic interest in the facilities to which they are sending their

Journal of Medicine (December 6, 1990). The Hillman study concluded that physicians with a financial interest in diagnostic imaging facilities referred patients at a rate of 4 to 4.5 times that of noninvesting physicians. Council Report, *Conflicts of Interest: Physician Ownership of Medical Facilities*, *Journal of the American Medical Association*, 267, 2366 (May 6, 1992).

A spokeswoman for the AMA said that this unusual conflict between the AMA House of Delegates and its Council on Ethical and Judicial Affairs is unlikely to be resolved until the December, 1992, meeting of the House of Delegates. Telephone interview with AMA's Public Information Office (July 7, 1992).

186. Rhonda Brammer, *Radiation Care is at the Center of the Storm Over Self-Referrals*, *Barron's*, 10 (March 30, 1992).

187. *Id.*

188. Waldholz and Bogdanich, *Wall Street Journal* at A1 (cited in note 1).

189. Brammer, *Barron's* at 11 (quoting Dr. Arnold Relman, former editor-in-chief of the *New England Journal of Medicine*).

190. *Id.*

191. *Id.*

patients won't influence their judgment.

Rampant entrepreneurship among physicians is a malady that requires strong medicine. It is an axiom of health care that patients trust their doctors to refer them to the best, most economical and most convenient clinic available. Disclosure requirements imposed by many states do not go far enough and are often ignored. With cutthroat competition for patients, doctors who control patient referrals can lock up the market and drive independent providers out of business. One home care service administrator from Montgomery, Alabama expressed this concern in a letter to Rep. Stark. She wrote,

Physician owned services in our area severely limit our ability to compete. Often patients are not given an opportunity to choose a home care service. Physicians refer their patients directly to their own company and the patient accepts that referral never knowing that another service is available. Realistically, even if physicians follow the AMA guidelines and inform patients about their financial involvement in a medical service to which they refer, the disclosure has little meaning. Human nature dictates that we must trust our doctor. After all, if we are willing to trust a doctor with our life, we have to believe that everything that doctor does for us is necessary and of the highest quality available. *People may ask their doctors questions, but they seldom question their doctors.*¹⁹²

The practice of self-referral raises three major policy concerns. First is the risk that physician-investors may not refer patients to the facility that provides the best care. Second, patients may be referred for costly services which are unnecessary. Finally, competition on price and quality of service is undermined. The Physician Self-Referral Amendments of 1992 proposed by Representatives Kasich and Santorum effectively address these policy concerns. This legislation should be endorsed by all who are opposed to abusive self-referral practices.

The storm over self-referrals is unlikely to blow over. The literal language of the federal anti-kickback statute provides room for broad judicial interpretation to prohibit self-referral practices. The trend toward increasing the scope of business practices which fall within the federal prohibitions is likely to continue as evidenced by the holdings in *Greber*, *Kats*, *Bay State*, and *Hanlester*. Since the safe harbor provisions were published in July, 1991, most individuals in the physician community have been trying to comply. Those who do not are at greater risk because it will become increasingly

192. HR 939, 101st Cong, 1st Sess, in 135 Cong Rec E 855 (March 20, 1989) (emphasis added).

more difficult to claim in court that the law is unclear. Federal regulators have vowed to be aggressive in pursuing doctors who violate the statute.¹⁹³ Finally, as studies such as that done in Florida reveal widespread abuse of self-referral practices, economic pressure brought on by skyrocketing health care costs will influence public sentiment and cause the judiciary, legislators, and regulators to act to further curb self-referral activity.

Carolyn M. Pengidore

193. Since October, 1987, the OIG has opened 838 cases of alleged kickback violations in the health care area. Physicians were involved in 460 of those. Nearly 600 have ended in settlements, exclusions, or penalties, including 83 criminal violations. Randall, *Journal of the American Medical Association*, 266, 2330 (November 6, 1991).